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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,546	02/10/2004	James E. Van Hoeck	4002-3480	6689
52196	7590	11/29/2006	EXAMINER	
KRIEG DEVault LLP ONE INDIANA SQUARE, SUITE 2800 INDIANAPOLIS, IN 46204-2709			ISABELLA, DAVID J	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/775,546.	HOECK ET AL.	
	Examiner	Art Unit	
	DAVID J. ISABELLA	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 11 September 2006.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-48, 58-69 is/are pending in the application.
 - 4a) Of the above claim(s) 21-48 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-20 and 58-69 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

Status of the Claims

Claims 21-57 remain withdrawn from consideration as being drawn to a non-elected species of the invention. Claims 49-57 have been cancelled without prejudice. Claims 59-69 have been newly added. Claims 1-20 and 58-69 are pending for action.

Response to Arguments

Applicant's arguments filed 9/11/2006 have been fully considered but they are not persuasive. Applicant has amended the claims to include the language of "

"two lateral walls, each having a flat lateral surface and integrally connected between said opposite ends of said anterior and posterior walls to define a chamber; and said anterior, posterior and lateral walls cooperating to define a D-shaped spacer body sized and configured to substantially fill the space between the vertebrae with said convexly curved anterior surface of said anterior wall sized and shaped to substantially conform to an anterior aspect of the space between the vertebrae;"

The claims as amended do not distinguish over the art of record. The prior art shows two lateral walls, each having a flat lateral surface. The claim fails to specifically define the "flat lateral surface as extending continuously from the anterior to the posterior wall. As broadly worded, the flat lateral surface may be interpreted as extending in the plane perpendicular to the AP plane. Moreover, the spacer of Brantigan (5192327) does illustrate a body comprising a wall having a convexly curved surface and opposite ends; an opposite wall having a flat surface and opposite ends; two lateral walls having flat surfaces, each integrally connected between said opposite ends of said walls to define a chamber; and said walls further defining; a superior vertebral engaging face defining a first opening, the opening in communication with the chamber; and an opposite vertebral engaging inferior face defining a second opening,

said second opening in communication with the chamber. Applicant should note that the structure of the device is identical to that as claimed.

With respect to claim 58 and the rejection to the claims over Kozak, applicant argues that the reference to Kozak is not a single piece. Contrary to applicant's assertion, the claim fails to define the device as a monolithic body. The claims as worded does not preclude the unitary body of Kozak that when each elements are integrally connected form a single "piece" spacer body

With respect to applicant's arguments to Brantigan, In response to applicant's argument directed to a method for employing the spacer, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

With respect to Heggeness (5514180) see similar arguments to each of Kozak and Brantigan supra.

Claim Rejections - 35 USC § 102

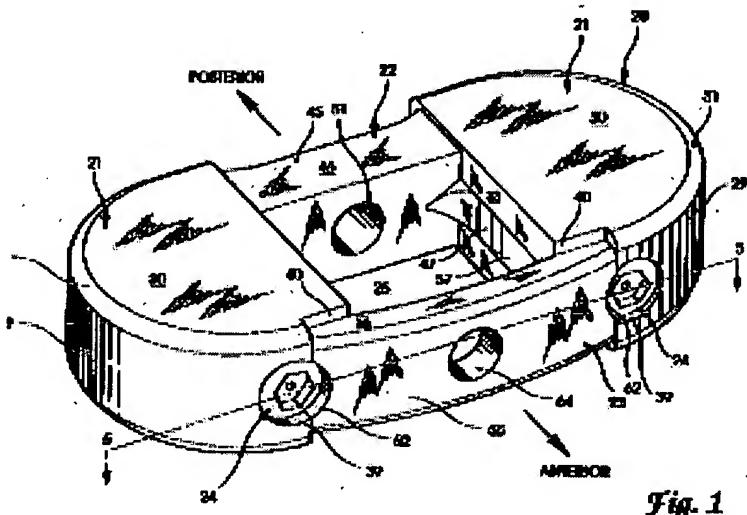
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,58 and 59,60 are rejected under 35 U.S.C. 102(b) as being anticipated by Kozak et al (5397364).

Kozak et al discloses, with respect to figure 1, discloses a hollow spinal spacer for engagement between vertebrae, comprising: an anterior wall having a convexly curved anterior surface and opposite ends; a posterior wall having a flat posterior surface and opposite ends; two lateral walls, each integrally connected between said opposite ends of said anterior and posterior walls to define a chamber; and said walls further defining; a superior vertebral engaging face defining a first opening, the opening in communication with the chamber; and an opposite vertebral engaging inferior face defining a second opening, said second opening in communication with the chamber. The lateral walls are flat in the direction perpendicular to the AP plane. The body of Kozak is a integral single piece body as broadly claimed. Note the claim does not define the body as a monolithic body.



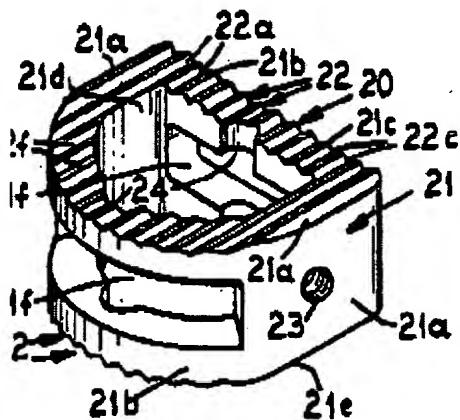
Claims 60 and 61, see apertures 64 and 52.

Claims 1,58, 59,60,63,64,65,68 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Brantigan (5192327)

Brantigan discloses, with respect to figure 2, discloses a hollow spinal spacer for engagement between vertebrae, comprising: an wall having a convexly curved surface and opposite ends; an opposite wall having a flat surface and opposite ends; two lateral walls, each integrally connected between said opposite ends of said walls to define a chamber; and said walls further defining; a superior vertebral engaging face defining a first opening, the opening in communication with the chamber; and an opposite vertebral engaging inferior face defining a second opening, said second opening in communication with the chamber. Applicant should note that the structure of the device is identical to that as claimed.

Orientation of the surfaces is determined by the method in which it is deployed in the body.

FIG. 2



Claim 59, the spacer body of Brantigan is monolithic.

Claims 60 and 65, the opening in the curved anterior wall may be grasped by an insertion tool.

Claims 63 and 68, see roughened surfaces of Brantigan.

Claim 64 and 69, the dimensional relationship between the length and width of the lateral surfaces appears to be within the range as claimed by applicant.

Claims 1-10, 12, 13, 17-18, 58, 59, 64 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Heggeness (5514180).

Heggeness discloses, with respect to figure 4, discloses a hollow spinal spacer for engagement between vertebrae, comprising: an anterior wall having a convexly curved anterior surface and opposite ends; a posterior wall having a flat posterior surface and opposite ends; two lateral walls, each integrally connected between said opposite ends of said anterior and posterior walls to define a chamber; and said walls further defining; a superior vertebral engaging face defining a first opening, the opening in communication with the chamber; and an opposite vertebral engaging inferior face defining a second opening, said second opening in communication with the chamber.

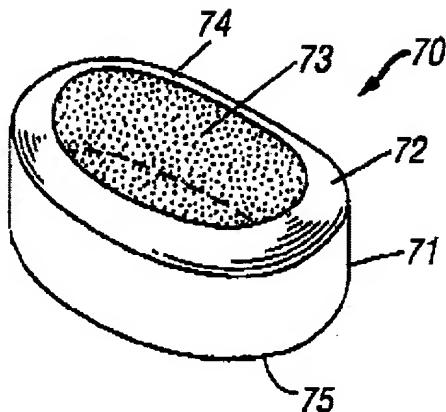


FIG. 24

Claims 2-10,12,13,17,18 see columns 10 & 11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heggeness (5514180) as applied to claim 10 above, and further in view of Silver et al (4703108).

The use of a matrix, in the form of a sponge, sheet and/or strip, is taught by Silver et al. To form the matrix in the form of a sheet to be inserted in the chamber of

Michelson such that the matrix is more easily inserted inside the chamber would have been obvious from the teachings of Silver et al.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heggeness (5514180) as applied to claim 10 above, and further in view of Wozney, et al (5366875).

Wozney et al teaches complexing the BMP with a carrier including polylactic acids and/or collagen for bone repair. To complex the BMP with a carrier to be placed in the chamber of Heggeness so as to provide inductive or conductive new tissue formation into the implant for securing the implant between the adjacent vertebrae would have been obvious from the teachings of Wozney, et al.

Claims 19,20,60-63,65-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heggeness (5514180) as applied to claim 10 above, and further in view of Michelson (5609635).

Michelson teaches the use of a threaded opening formed in the implant configured to fit onto a driving end of a insertion instrument to assist in the placement of the implant between the vertebrae. To form a threaded opening in the implant of Heggeness to assist the surgeon in the placement of the implant between the vertebrae would have been obvious from the teachings of Michelson.

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The method of inserting the implant 100 is set forth in detail in application Ser. No. 08/263,952, incorporated herein by reference. The threaded end of a driving instrument is attached to the threaded opening 126 in the trailing end 120 of the implant 100 and the fitting of the driving instrument into the depressed portion 124 prevents movement of the implant 100 in relationship to the driving instrument. The implant 100 is then placed at the entrance to the disc space between the two adjacent vertebrae V. The driver instrument is then tapped with a hammer sufficiently hard enough to drive the implant 100 into the disc space.

With respect to claim 20, Michelson teaches using roughen external surfaces of the implant to provide for better anchoring/fixation of the implant between the vertebrae.

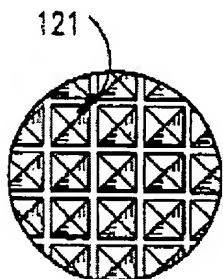


FIG 7

The upper and lower surfaces 112 and 114 of the implant 100 may be flat or curved to conform to the shape of the end plates of the adjacent vertebrae between which the implant 100 is inserted. The implant 100 conforms to the shape of the nucleus pulposus and a portion of the annulus fibrosus removed from the vertebrae. The upper and lower surfaces 112 and 114 comprise surface roughenings that provide a surface suitable for engaging the adjacent vertebrae to stabilize the implant 100 within the disc space once surgically implanted. The surface roughenings of the upper and lower surfaces 112 and 114 comprise a surface knowing 121.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

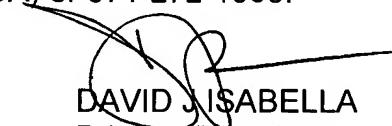
§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 571-272-4749. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



DAVID J. ISABELLA
Primary Examiner
Art Unit 3738

DJI
11/22/2006